

REMARKS

Reconsideration is respectfully requested.

Claims 1 through 12, 33 through 35, 37 through 39 and 42 through 45 remain in this application. Claims 13 through 32, 36, 40, and 41 have been cancelled. No claims have been withdrawn. Claims 46 through 48 have been added.

Parts 1 through 6 of the Office Action

Claims 1 through 9, 33 through 35, 37 through 39, 42, 44 and 45 have been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Swann in view of Hupee.

Claims 1 through 6, 9, 33 through 35, 37 through 39, 42, 44 and 45 have been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Akers in view of Berg.

Claim 10 has been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Swann in view of Huppee as applied to claims 1 through 9, 33 through 35, 37 through 39, 42, 44 and 45, and further in view of Lake.

Claim 7 has been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Swann in view of Huppee as applied to claims 1 through 9, 33 through 35, 37 through 39, 42, 44 and 45, and further in view of Baudino.

Claim 12 has been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Swann in view of Huppee as applied to claims 1 through 9, 33 through 35, 37 through 39, 42, 44 and 45, and further in view of McNeil.

Claim 43 has been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Swann in view of Huppee as applied to claims 1 through 9, 33 through 35, 37 through 39, 42, 44 and 45, and further in view of Lake, further in view of Baudino and further in view of McNeil.

Initially, it is noted that three of the rejections in the Office Action rely upon the alleged obviousness of the modification of the Swann device with selected elements of the Huppee device. It is conceded in the rejection of the Office Action that:

Swann et al. fails to disclose a retaining means on the exterior surface of the tubular portion adjacent to the distal end for engaging an interior surface of a conduit with a flexible wall to releasably retain the conduit on the distal end of the tubular portion.

It is then asserted in the Office Action that:

Huppee discloses a barbed tubing connector (10) comprising a tubular portion (12) including retaining means (18) on the exterior surface of the tubular portion adjacent to the distal end for engaging an interior surface of a conduit with a flexible wall to releasably retain the conduit on the distal end of the tubular portion.

and further that:

It would have been obvious to one having ordinary skill in the art to have modified Swann et al. with a retaining means as taught by Huppee so as to enable higher operating pressures while maintaining a leak free connection without the need for complex connection means on the cooperating end of the flexible conduit.

However, for the following reasons, it is submitted that one of ordinary skill in the art, considering the teaching of the Swann patent, would not look to the Huppee patent for modifications or improvements on the Swann device. In particular, in the allegedly obvious combination, the male connection of the Huppee device is substituted for the female connection of the Swann device. But the Swann patent clearly teaches against the use of a male connection on its end, which is the type of connection that Huppee shows.

More specifically, the Swann patent states at col. 1, lines 55 through 66 the basic objectives of the device (emphasis added):

The basic objectives of this invention are to provide a device that features (1) increased stability within the skull, (2) increased safety with a device to prevent plunging into the brain during and after insertion into the skull, (3) adjustability to the varied skull thicknesses found among patients, (4) the ability to accurately measure the depth of the subarachnoid space with a depth gauge and to place the tip of the device exactly at the desired location, (5) design elements to prevent plugging of the device during insertion such as a metallic stylette and (6) a female luer port that allows the easy attachment of only one stopcock to the device.

Thus, the Swann patent makes clear to one of ordinary skill in the art considering it that providing a female connection is one of its objectives.

The importance of the female luer port to the Swann device, *and the advantage of the female connector over a male connector*, is further described at col. 4, lines 46 through 54, where Swann states that (emphasis added):

A female luer at the proximal end of the Swann-Cosman Bolt allows the use of a single stopcock for attachment of transducer tubing and a flushing syringe. The Richmond Bolt has a male end which requires two stopcocks in tandem. An extra stopcock is undesirable as it increases the bulk of the device and adds more unused ports which increases the potential for contamination.

Thus, contrary to the assertion in the rejection that the allegedly obvious combination would provide “a leak free connection without the need for complex connection means”, the Swann patent states that its female connection provides a simpler and less bulky device. Thus it is submitted that the rationale for the combination that is set forth in the rejection is directly contrary to the literal teaching in Swann. It is therefore submitted that one of ordinary skill in the art, considering the disclosure of Swann (and without knowledge of the applicant’s disclosure), would not seek to replace the female luer port with a male coupling means of the type shown in Huppee, as suggested in the rejection of the Office Action.

Further, the Swann patent does not disclose any desirability or need for operation at “higher operating pressures” (as alleged in the Office Action). More importantly, one of ordinary skill in the art recognizes that the “operating pressures” encountered by the Swann device are deminimus, as any significant pressures that might be encountered by the Swann device would result in the death or severe brain damage of the patient. Pressures above what the Swann device could handle don’t exist in the environment of its use, which is the brain cavity. Also, nothing in Swann (or Huppee, for that matter), suggests that the female luer port employed in Swann is in any way insufficient or inadequate to control the pressures encountered in its environment, particularly the intracranial area. The rejection also fails to provide any basis for the inference that the male connection of Huppee is able to handle higher pressures than the female luer connection set forth in Swann, as the Huppee patent does not compare the performance of its male connection to any female luer connection such as is advocated by Swann.

Still further, the Huppee patent fails to include any suggestion of any usefulness of its features on surgical devices. Again, the Huppee disclosure is directed to increasing the resistance to leaks at higher pressures—pressures that would not be encountered by the Swann device in its intended surgical application. This raises the question: Why would one of ordinary skill in the art seek to modify the Swann device to accommodate pressures it will never encounter.

It is therefore submitted that the rejection does not make the case that one of ordinary skill in the art, considering the actual teaching of the Swann and Huppee patents, would be motivated to make the allegedly obvious modification of Swann.

It is also noted that three of the rejections in the Office Action rely upon the alleged obviousness of the modification of the Akers device with selected elements of the Berg device. Initially, it is recognized in the

rejections based upon the allegedly obvious combination of Akers and Berg that:

Akers failed to disclose a pair of wings for facilitating finger rotation of the tubular portion, the wings extending outwardly from the tubular portion in substantially opposite directions from the tubular portion.

It is then contended in the rejection that:

Berg discloses a tap comprising a tubular portion (11) including a pair of wings (14, 14') for facilitating finger rotation of the tubular portion, the wings extending outwardly from the tubular portion in substantially opposite directions from the tubular portion.

and it then alleged that:

It would have been obvious to one having ordinary skill in the art to have modified Akers connector with a pair of wings as taught by Berg to provide means for providing torque to the connector so as to aid in manually threading the connector into the opening.

For the following reasons, it is believed that one of ordinary skill in the art, considering the actual teachings of the Aker and Berg patents, would not be led to make the allegedly obvious modification of the Akers device with the elements of Berg. In particular, the Aker patent discloses a hexagonal flange on its tank connector to be engaged by a wrench for rotating the device and forcing the device into the hole. Specifically, the Akers patent discloses a "self-sealing tank connector" that includes "square-cut starting threads" for "distorting" (not cutting) the material of the wall of the tank. See, for example, Aker at col. 1, lines 56 through 62 (emphasis added):

As the tapered threaded section is screwed into the aperture, the tank wall is initially deformed or distorted by the flat-topped threads and is then led or directed into the relief section to captivate the connector against removal even if the fitting is subsequently rotated in either direction. The gasket, held between the flange section and the wall, provides a fluid-tight seal.

Akers is clear as to what feature of the device permits this distorting without cutting. See, for example, Akers at col. 2, lines 68 through 71 (emphasis added):

Of course, the polygonal shape (six sided in the illustrated embodiment) of flange section 24 allows the use of a wrench for rotating the fitting to simplify further the process of screwing the fitting into the tank wall.

Thus one of ordinary skill in the art, considering Akers, understands that the flange is used to drive the device into the hole, which since the deformation of the wall of the tank is required, clearly requires a significant amount of rotational force.

Although the rejection is not clear as to the form of the allegedly obvious combination, it would appear that the combination would entail replacement of the flange of Akers with the "thumb members" of Berg, or the addition of the "thumb members" Berg to the Akers tank connector. However, it is submitted that one of ordinary skill in the art considering Akers would recognize that any attempt to add the "thumb members" of Berg to the flange of Akers would destroy the ability of a wrench to engage the flange in any effective manner. (Alternatively, placing the thumb members on the barbed section would reduce the ability to of the barbs to penetrate the tubing.) It is submitted that one of ordinary skill in the art would not modify the Akers device in a manner that would prevent the primary manner of rotating the device—namely a wrench--from being used.

Further, it is submitted that one of ordinary skill in the art would recognize that replacing the hexagonal flange with the thumb members of Berg is also not a suitable option, as the thumb members (and the users bare hands) would provide insufficient leverage for rotating the Aker device so that it would be able to generate enough torque to distort the wall of the tank with the flat-topped threads. The text of Berg clearly teaches "thumb members 14 and 14'" for being engaged by the thumb or fingers of the user to rotate the tap. It is therefore submitted that one of ordinary skill in the art, considering the teachings of the Akers and Berg patents, would not be

motivated to make the allegedly obvious combination suggested in the rejection of the Office Action.

Also, claims 3, 5, 6, 42, and 43 each require “self-tapping threads formed thereon adapted for cutting threads into the opening in the skull of a patient”, which is in clear contradiction to the teaching in Akers of “flat-topped threads” that avoid “cutting or grinding material from the peripheral edge of the aperture” (see Aker at col. 2, lines 38 et seq.). Since the Aker teaching is in contradiction to this requirement of these claims, it is submitted that Akers could not lead one of ordinary skill in the art to these requirements.

Further, with respect to the various allegedly obvious combinations of the tertiary patents with the allegedly obvious combination of Swann and Huppee, it is noted that the Swann patent is directed to an “intercranial pressure measuring screw”, and not any type of intercranial drain. Yet the portions of the rejections seeking to suggest a motivation for the combination of Baudino with Swann and Huppee states that:

[INSERT QUOTE FROM OA]

However, the device of the Swann patent has no indication that it is to be used in providing any drainage of fluid, and is as mentioned above is directed to pressure measuring. Baudino is primarily directed to introducing fluids into the intercranial space, but does include some mention of withdrawing fluids. However, it is submitted that the rejection does not indicate why one of ordinary skill in the art would be motivated to apply elements of a fluid drainage device to a pressure monitoring system, especially when the drainage function could interfere with the pressure measuring function of Swann. It appears that the rejection is based upon the abandonment of the pressure measuring function of Swann for a secondary use for the Baudino device. It is submitted that one of ordinary

Appln. No. 09/633,573

Amendment dated April 17, 2006

Reply to Office Action mailed November 17, 2005

skill in the art would not have made such a modification of function of the Swann device.

It is therefore submitted that the cited patents, and especially the allegedly obvious combination of Swann and Huppee set forth in the rejection of the Office Action, would not lead one skilled in the art to the applicant's invention as required by claims 1, 5, 6, 42 and 45. Further, claims 2 through 4, 33, 34, and 44 which depend from claim 1, and claims 7, 9, 11, 37, 38 and 43 which depend from claim 6, also include the requirements discussed above and therefore are also submitted to be in condition for allowance.

Withdrawal of the §103(a) rejections of claims 1 through 9, 10, 12, 33 through 35, 37 through 39, and 42 through 45 is therefore respectfully requested.

CONCLUSION

In light of the foregoing amendments and remarks, early reconsideration and allowance of this application are most courteously solicited.

Respectfully submitted,

WOODS, FULLER, SHULTZ & SMITH P.C.



Jeffrey A. Proehl (Reg. No. 35,987)

Customer No. **40,158**

P.O. Box 5027

Sioux Falls, SD 57117-5027

(605)336-3890 FAX (605)339-3357

Date: April 17, 2006